

- [0036] Fig. 10 shows an inventive device including inflatable members disposed end to end along the balloon.
- [0037] Fig. 11a shows an inventive device with inflatable members disposed spirally about a balloon.
- [0038] Fig. 11b shows a perspective of a balloon configured with the device of Fig. 11a.
- [0039] Fig. 12 shows a perspective of an inventive device with a balloon disposed therein.
- [0040] Fig. 13 shows a perspective view of the inventive device of Fig. 12 with the inflatable members inflated to produce a plurality of wings in the balloon.
- [0041] Fig. 14 shows a cross-sectional view of the inventive device of Fig. 13 taken along line 14-14.
- [0042] Fig. 15 shows a perspective of an inventive device for configuring an inflatable balloon in accordance with another embodiment of the invention.
- [0043] Fig. 16 shows a perspective view of the rigid tube and inflatable member of Fig. 15 with parts cut-away.
- [0044] Fig. 17 shows a cross-sectional view of the rigid tube and inflatable member of Fig. 16 taken along line 17-17.
- [0045] Fig. 18 shows the cross-sectional view of Fig. 17 with the inflatable member at least partially inflated.
- [0046] Fig. 19 shows a cross-sectional view of Fig. 18 with the inflatable member inflated and forming a plurality of wings in a balloon.
- [0047] Fig. 20 shows a perspective view of an inflatable member with parts cut-away.
- [0048] Fig. 21 shows a cross-sectional view of the device of Fig. 14 taken along line 21-21 with parts cut away.
- [0049] Fig. 22 shows a cross-sectional view of another embodiment of the invention.
- [0050] Fig. 23 shows a cross-sectional view of the embodiment of Fig. 22 upon further inflation of the inflatable members.

- [0051] Fig. 24 shows a side elevational view of an inventive medical balloon.
- [0052] Fig. 25 shows a cross-sectional view of an inventive device for configuring medical balloons.
- [0053] Fig. 26 shows a perspective view of a die.

Detailed Description

- [0054] While this invention may be embodied in many different forms, there are shown in the drawings and described in detail herein specific embodiments of the invention. The present disclosure is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.
- [0055] For the purposes of this disclosure, unless otherwise indicated, identical reference numerals used in different figures refer to the same component.
- [0056] In one embodiment, the invention is directed to a device such as that shown generally at 100 in Figs. 1–3, 6 and 7 for configuring an inflatable balloon 104 of a balloon catheter assembly 108. Balloon catheter assembly 108 comprises catheter tube 109 and balloon 104 disposed thereabout. Device 100 comprises a body 112 with a plurality of inflatable members 116 defining a channel 120 therebetween. In this embodiment, inflatable members 116 are disposed about the circumference of a circle, as shown in Fig. 3. Channel 120 is sized to accommodate at least a portion and desirably, the entirety of balloon 104 of balloon catheter 108 therein. Each inflatable member 116 has a balloon contacting portion 124. Device 100 typically comprises from three to six inflatable members 116. Additional inflatable members 116 may be provided. The invention contemplates providing at least one inflatable member.
- [0057] Inflatable members 116 may take on any configuration to provide an appropriate balloon contacting portion. Some non-limiting examples of suitable configurations include a generally tubular inflatable member having a wedge-shaped cross-section as shown in Fig. 3, a generally pie-shaped section as shown in Fig. 4, a circular cross-section as shown in Fig. 5 and a V-shaped cross-section (not shown). Typically, the balloon contacting portion will be rounded, radiused, pointed, flat or of other suitable shape regardless of the shape of the non-contact surface.
- [0058] Inflatable members 116 may be in the form of a thick walled silicone tube capable of

withstanding multiple inflation and deflation cycles. Inflatable member 116 may also be made of any other suitable balloon materials including compliant and non-compliant materials such as latex, polyethylene terephthalate (PET), polyethylene, nylon and polyvinyl chloride. The inflatable member may be made of the same material as the balloon which is to be configured or may be made of a different material. In the former case, the inflatable member must be inflated to a pressure exceeding that of the balloon as the balloon is configured. Optionally, the inflatable member will be made of a material which is harder and/or more rigid than the balloon to be folded. Materials which are softer and/or less rigid than the balloon may also be used.

[0059] Inflatable members 116 are supplied with a compressible or non-compressible inflation fluid via inflation lumens 119. As shown in Fig. 8, inflation lumen 119 typically opens into inflatable member 116 via an inflation port 117 which is located at a first end of the inventive device. Balloon 104 is supplied with a compressible or non-compressible inflation fluid via inflation lumen 120 which opens into balloon 104 via inflation port 123 at a second end of the device generally opposite the first end of the device. With this arrangement of inflation ports, inflatable members 116 may configure balloon 104 progressively along the length of the balloon from the first end of the balloon to the second end of the balloon, with inflation fluid gradually forced out inflation port 123. The arrangement of having inflation port 123 of inflatable member 116 and balloon 104 at opposing ends allows for optimal removal of balloon inflation fluid. The gradual bleeding of inflation fluid from a single end of the balloon reduces the likelihood of formation of bulges or bubbles in the balloon.

[0060] The inventive devices may also be provided in embodiments, such as that shown generally at 100 in Fig. 9, in which inflatable members 116 are held at an oblique angle relative to the longitudinal axis of balloon 104. As inflatable members 116 are inflated, balloon is gradually configured along its length and the inflation fluid in balloon 104 forced to exit from inflation port 123 opposite to where configuring of the balloon commences.

[0061] Alternatively, as shown in Fig. 9a, inflatable members 116 may also be angled so that as it is expanded, the closed end of balloon 104 is compressed first and the lumen end of balloon 104 is compressed last.

[0062] Other arrangements of the inflation ports are also within the scope of the invention.